

# Notice of Allowability

## Application No.

09/735,271

## Examiner

Jehanne E Souaya

## Applicant(s)

DALY ET AL.

## Art Unit

1634

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/7/2003.
2. ☒ The allowed claim(s) is/are 7,9,10 and 12.
3. ☒ The drawings filed on 11 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____  |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|  | 9 <input type="checkbox"/> Other  |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa Treannie on April 14, 2003.

The application has been amended as follows:

Please amend the title as follows:

Delete "IBD-Related Polymorphisms" and insert instead --Crohn's Disease Related Polymorphisms--

Please amend the specification as follows:

At page 108 of the specification, please delete the designation ">IGR2063a" and replace with -->IGR2063b--.

Claim 7. (Twice amended) A method of predicting the likelihood that an individual is susceptible to [will have] Crohn's disease, comprising the steps of:

- a) obtaining a DNA sample from an individual to be assessed; and
- b) determining the nucleotide present at nucleotide position 218 relative to the 5' most nucleic acid in SEQ ID NO: 1127,

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wherein the presence of a guanine at nucleotide position 218 is indicative of a greater likelihood of susceptibility to Crohn's disease in the individual as compared with an individual having a cytosine at nucleotide position 218.

Claim 9. (Twice amended) A method according to claim 7, wherein the individual to be assessed is an individual at risk for development of Crohn's disease.

Claim 10. (Twice amended) A method of predicting the likelihood that an individual is susceptible to [will have] Crohn's disease, comprising the steps of:

- a) obtaining a DNA sample from an individual to be assessed; and
- b) determining the nucleotide present at nucleotide position 218 relative to the 5' most nucleic acid in SEQ ID NO: 1127,

wherein the presence of a cytosine at nucleotide position 218 is indicative of a reduced likelihood of susceptibility to Crohn's disease in the individual as compared with an individual having a guanine at nucleotide position 218.

Claim 12. (Twice amended) A method according to claim 10, wherein the individual to be assessed is an individual at risk for development of Crohn's disease.

Support for the amendments can be found in the specification at page 10, lines 10-13; and page 23, lines 12-15.

### REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: the claims are drawn to a method of predicting the likelihood that an individual is susceptible to Crohn's disease, comprising the steps of obtaining a sample of DNA from the individual to be assessed; and determining the nucleotide present at position 218 relative to the 5' most nucleic acid in SEQ ID NO 1127, wherein the presence of a guanine at nucleotide position 218 is indicative of a greater likelihood that the individual is susceptible to Crohn's disease as compared with an individual having a cytosine at nucleotide position 218 or wherein the presence of a cytosine at nucleotide position 218 is indicative of a decreased likelihood that an individual is susceptible to Crohn's disease as compared with an individual having a guanine at nucleotide position 218. The claims are further drawn to such methods wherein the individual is an individual at risk for development of Crohn's disease.

The specification teaches that a G instead of a C at position 218 of SEQ ID NO: 1127 has a statistically significant association with Crohn's Disease (see Table 4, 3<sup>rd</sup> row). The claims are allowable over the prior art because the prior art does not teach or fairly suggest an association between the claimed polymorphism and Crohn's disease.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne Souaya  
Patent examiner  
Art Unit 1634

4/14/03